



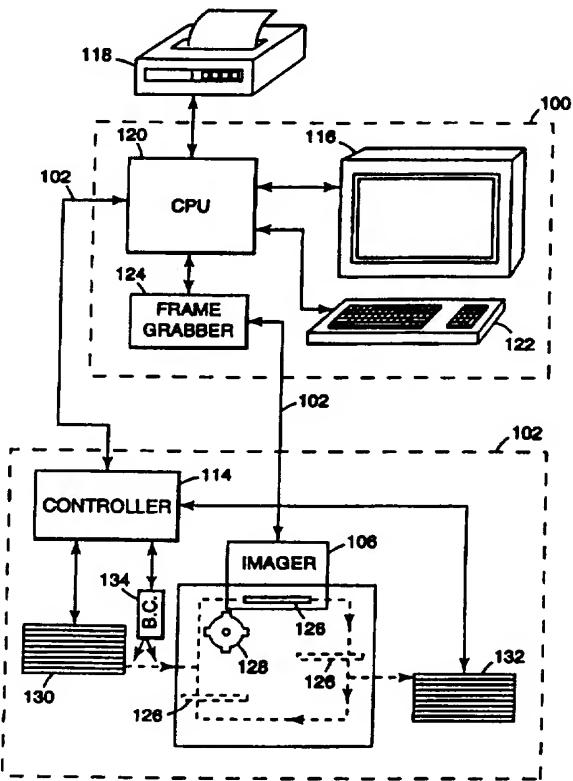
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## (54) Title: METHOD AND APPARATUS FOR GRAPHICALLY IDENTIFYING COUNTS OF MICROORGANISMS

## (57) Abstract

A method and apparatus for displaying a microorganism culturing device is provided. A digitized image is electronically captured from a disposable microorganism culturing device. Growing microorganism colonies in the culturing device are enumerated into a colony count and this colony count is stored into a database. In addition, the digitized image and colony count are displayed.



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## METHOD AND APPARATUS FOR GRAPHICALLY IDENTIFYING COUNTS OF MICROORGANISMS

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### BACKGROUND

The present invention relates generally to a method and apparatus for processing and displaying digitized images of microbial culturing devices. More particularly, the present invention relates to graphically enumerating 10 microorganisms in a sample on a disposable microorganism culturing device and electronically displaying digitized images of the culturing device.

Different methods and devices are known for counting microorganism colonies in a nutrient media. This nutrient media, such as agar, may be placed in a petri dish or on a disposable microorganism culturing device such as a PETRIFILM 15 thin film culture plate, manufactured by Minnesota Mining and Manufacturing Company, St. Paul, MN (3M). Manual counting of microorganism colonies in culturing plate devices by trained laboratory personnel is well-known. Typically, a culture plate device (e.g., a PETRIFILM thin film plate) is inoculated with a particular sample, marked to identify the inoculant sample source, stacked together 20 with similarly inoculated devices, and placed into an incubator. A manual inspection and counting is typically performed after a period of about 24 hours (commonly known as Quebec counting). This method has known disadvantages, particularly the costs associated with the use of skilled technicians to perform time-consuming manual counting.

25 Automated systems for counting microorganisms in a sample are also known, but are typically directed at producing total counts of microorganisms grown in media that has been incubated for 24 hours or more. One example of such a system is described in a bio-Foss Colony Counting System brochure from Foss Food Technology Corporation, Eden Prairie, MN. The bio-Foss system 30 digitally detects colonies in an incubated sample placed under a camera and displays the count on a computer video screen.

Another type of automated system is the Bactometer available from bioMérieux Vitek, Inc., Hazelwood, MO. The Bactometer measures a change in electrical conductance of a specimen held in a tray. This measurement can be repeated at time intervals for the same specimen to determine growth patterns of 5 microorganisms.

Yet another automated system for counting microorganisms is described in U.S. Patent No. 5,290,701 (Wilkins) entitled "Microbial Detection System and Process". This patent reports an automated system for monitoring the growth of vertically oriented subsurface colonies with a video camera, image processor, and 10 computerized control circuitry and indicates that many types of output are desirable, but fails to teach any preferred graphical user interface for controlling the system or for providing data output to a user.

Early detection of colonies is also desirable in the matter of microbiological counting, particularly when food products are being tested. If food product 15 samples indicate excessive contamination, the product must often be discarded. Reliable early detection of excessive contamination in the range of 6 to 12 hours after inoculation would be welcome because it would allow identification of contaminated products early in processing, thereby avoiding additional expenses incurred in processing products that will be discarded and possibly contaminate 20 additional products by running them through contaminated processing equipment.

Examples of improved microbiological counting systems are reported in PCT International Publication No. WO 94/01528 (Floeder et al.), U.S. Patent No. 5,403,722 (Floeder et al.), PCT International Publication No. WO 94/26870 (Morgan), and PCT International Publication No. WO 95/16768 (Krejcarek et al.). 25 Floeder et al. report an improved microbiological counting system that includes methods and apparatus for automated counting of objects in a scanned image. Morgan reports a method for early detection of colony growth on a planar substrate by scanning and imaging an inoculated surface more than once as well as processing the images to produce a scaled time lapse image. In addition, Krejcarek et al. 30 report an automated control system for a multi-device incubator and imaging apparatus that uses a disposable microorganism culturing device.

However, these counting systems do not describe a preferred user interface which allows easy and sophisticated operation of the counting and culturing system and manipulation of the results to meet the needs of various types of end users including food processing plant technicians, plant/health inspectors, state agencies, 5 or the like.

Some components of a user interface for use in such a system are known. For example, an advertisement by KAIROS, Inc., Mountain View, CA, depicts a screen showing a digitized image of a culturing device. Also, literature by Dipix Technologies, Inc., Ottawa, Ontario, Canada, describes a microscope-based image 10 digitizer system which may be used in detection of yeast colonies. This Dipix system describes a video pass through circuit which allows a user to view a portion of a sample as it is being imaged; however, an image of the whole sample is not shown to a user during any operation of the Dipix system. In short, a need still exists for an improved user interface which allows quick and easy operation of a 15 microbial counting and culturing system.

#### SUMMARY OF THE INVENTION

The present invention overcomes the above-identified limitations in the field by providing a method and apparatus for displaying a microbial culture plate device. 20 In a preferred embodiment, a digitized image is electronically captured from a disposable, thin film culture plate device. The microorganism colonies in the digitized image are enumerated by a data processor into a colony count value. This colony count along with a time of capturing the digitized image and an origin for the digitized image is stored into a database. The use of a database in this scheme 25 provides tremendous flexibility and the ability to provide many desirable data processing features such as statistical analysis and reporting functions.

The stored colony count value may be compared to a selected predetermined value that is related to known parameters for the sample type being tested (e.g., a milk sample is compared to industry standards for colony count 30 values in milk). Subsequently, the digitized image, the colony count value, and an associated status indicator are displayed on a computer monitor or similar device.

The particular status indicator, which is displayed, will depend on a result of the comparison to the predetermined value. For example, an alarm indicator may be displayed, if the colony count value is greater than the predetermined value. In addition, a warning indicator may be displayed when the colony count value is less than the predetermined value, if the count value is approaching the predetermined value or if the count value has increased above a particular rate over a predetermined time (i.e., the colony count values are increasing rapidly). Finally, an okay indicator may be displayed if the colony count value is still less than the predetermined value after a specified predetermined time limit has lapsed (i.e., the 5 incubation time is done).

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This procedure for displaying a culturing device may repeat periodically for the same disposable microorganism culturing device such that colony count values for several instances in time are obtained and stored in the database. Alternatively, this procedure for displaying a culturing device may be repeated for a plurality of 15 disposable microorganism culturing devices such that several colony count values may be simultaneously displayed along with a summary section which details a status on each of the plurality of disposable microorganism culturing devices. Another way this procedure may be used is for post incubation detection. In post incubation detection a group of incubated disposable microorganism culturing 20 devices are input to the system to be incubated or after incubation has occurred (e.g., 24, 48, or 72 hours) and subsequently a single colony count is derived for each culturing device. This single colony count is then stored in the database.

Another aspect of this displaying procedure is to provide a mechanism for manual verification which is similar to the prior technique of counting colonies by 25 picking them out of a petri dish. This electronic form of manual verification is provided by marking a colony location with an input device (e.g., a light pen, mouse, trackball, or touch screen,) on the displayed digitized image with a visual count being incremented automatically for each marked colony.

These and various other features as well as advantages which characterize 30 the present invention will be apparent upon reading of the following detailed description and review of the associated drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a diagram of a preferred embodiment apparatus for graphically enumerating microorganisms in a sample and displaying the results in accordance with the present invention.

5 FIG. 2 is a more detailed diagram of the preferred embodiment apparatus in accordance with the present invention shown in FIG. 1.

FIG. 3 is a flow diagram of a preferred embodiment user interface for use in accordance with the present invention shown in FIG. 1.

10 FIGs. 4, 5, 6, 7, 8 and 9 are screen displays of the preferred embodiment user interface which are displayed in accordance with the flow diagram shown in FIG. 3.

FIGs. 10 and 11 are a flowchart describing the operation of the preferred embodiment user interface in accordance with the present invention shown in FIG. 1.

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**DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT**

FIGs. 1 and 2 illustrate a preferred embodiment system for graphically enumerating microorganisms in a sample and displaying the results in accordance with the present invention. The system includes an incubator 102, which has mounted on it an imager 106, a shelf 108 adapted for supporting disposable microorganism culturing device holders 126 which are to be inserted into the incubator 102, an enclosure 110 for an input mechanism 130 for introducing holders on the shelf 108 into the incubator 102, and a hopper 112 for receiving holders that have been ejected from the incubator 102 by output mechanism 132. In addition, a controller unit 114 is mounted in the incubator 102 for controlling the operations within the incubator. This controller is connected by a data communication link 104 to a microprocessor/ computing device 100. Microprocessor 100 preferably is a multitasking computer that works in conjunction with controller 114 to provide several control functions, including mechanisms 128 for moving and queuing holders within the incubator 102, for timing the taking of images by a imager/camera 106, and for enumerating microorganism colonies.

In the preferred embodiment, the computing device 100 includes an 80486 Intel microprocessor-based personal computer which is running Windows 3.1 (an operating system environment commercially available from Microsoft Corporation), and a compiled program that runs under the Windows 3.1 operating system. This 5 compiled program was developed under Visual C++ 1.5 Professional and Visual Basic 3.0 Professional (software development tools commercially available from Microsoft Corporation), and Microsoft Access (a database software package commercially available from Microsoft Corporation). However, it will be appreciated by those skilled in the art that other types of computers and/or software 10 may be used to duplicate the operations and user interface described herein without departing from the scope and spirit of the present invention.

Referring now more particularly to FIG. 2, a printer 118 optionally may be attached to computer 100 for providing hard copies of reports or visual displays provided by the computer. In addition, computer 100 preferably includes a central 15 processing unit (CPU) or microprocessor 120 which is operatively coupled to other components of computer 100 including a visual display/monitor 116, keyboard input device 122, and frame grabber board 124 which works in conjunction (via data link 102) with imager/camera 106 to electronically capture digitized images of a disposable microorganism culturing device contained in holder 126. Further, as 20 described above incubator 102 includes several components including imager 106, controller 114, culturing device holders 126, motivating mechanism 128, input mechanism 130, and output mechanism 132. The operations of the incubator 102 may be enhanced by the addition of a bar code reader 134. Additionally, bar code 25 reader 134 may be used to automatically identify particular holders 126 which enter the incubator 102 so that a user need not manually enter identifying information by keyboard 122. The particular operations of the preferred embodiment incubator 102 are more specifically described in the above-noted related invention as described in PCT International Publication No. WO 95/16768 (Krejcarek et al.). Also, the particular operations of imager 106, CPU 120, and frame grabber 124 30 related to counting of microorganism colonies are more specifically described in the above-noted related inventions as described in PCT International Publication No.

WO 94/26870 (Morgan) and U.S. Patent Application Serial No. 08/356,484 (Braier et al.).

PCT International Publication No. WO 94/26870 (Morgan) describes a method for the early detection and counting of microorganism colonies in an 5 inoculated growth medium. This detection is accomplished by imaging the growth medium to obtain a first colony image, incubating the growth medium for a time interval, and imaging the growth medium to obtain a second colony image. Subsequently, the first and second colony images are processed to produce a raw 10 time lapse image. This raw time lapse image is analyzed to identify hit pixels and these hit pixels are clustered to identify microorganism colonies appearing in the growth medium between the first and second colony images. The identified 15 microorganism colonies are totaled to generate a total count.

The production of the raw time lapse image preferably includes subtracting the first colony image from the second colony image to produce the raw time lapse 15 image and rescaling the raw time lapse image to produce a scaled time lapse image. Local minima in the scaled time lapse image are identified as the hit pixels. Local minima are determined by testing a value at a center pixel for compliance with a threshold value, testing at least two directly adjacent neighboring pixels to insure that they have a value greater than said center pixel value, testing pixels located 20 adjacent to each of the neighboring pixels and opposite from the center pixel to insure that they have a value greater than the value of their adjacent neighboring pixel, and labeling each center pixel which satisfies these tests as a local minima.

Previously identified microorganism colonies preferably are enlarged by scaling the time lapse image, comparing the value of inner pixels lying on a 25 perimeter of the previously identified microorganism colonies with the value of corresponding outer pixels lying adjacent the inner pixels and outside the perimeter, and enlarging the previously identified microorganism colonies which have at least two inner pixels with a value less than the corresponding outer pixels.

The process of early detection and counting of microorganism colonies may 30 be further enhanced by generating a mask image through identifying pixels in the

mask image which lie outside of the growth medium and preventing any further processing of the pixels which lie outside of the growth medium.

U.S. Patent Application Serial No. 08/356,484 (Braier et al.) describes a method and apparatus for detecting and identifying microbial colonies in an inoculated growth medium. This detection is accomplished by imaging the growth medium to obtain first colony image data. Subsequently, the growth medium is incubated for a selected time interval and again imaged to obtain second colony image data. Then, the first and second colony images are processed to produce a difference image which is the difference between the first colony image data and the second colony image data. Potential colonies are identified with a peak pixel and a colony radius within the difference image. Finally, each potential colony is validated by eliminating the colony as a potential colony if the potential colony is a noise spike or noise around the perimeter of a previously validated colony.

The potential colony preferably is identified as a noise spike and eliminated as a potential colony when a peak pixel intensity value of the potential colony exceeds a spike peak threshold value and a colony radius of the potential colony does not exceed a spike radius threshold value. Alternatively, the potential colony may be identified as a noise spike and eliminated as a potential colony when a value derived from a peak pixel intensity and a colony radius of the potential colony exceeds a spike peak value.

The potential colony preferably is identified as noise around the perimeter of a previously validated colony and eliminated as a potential colony when not validated. The potential colony validation preferably occurs by identifying a validated colony closest to the potential colony having the largest peak pixel intensity value. The closest validated colony preferably is identified by defining an outer edge of each validated colony based on the peak pixel and the colony radius of each validated colony, defining a potential outer edge of the potential colony based on the peak pixel and the colony radius of the potential colony, and labeling the validated colony with an outer edge closest to the potential colony outer edge as the closest validated colony. Then, a noise radius is computed for the closest validated colony and the potential colony is validated if the potential colony is

outside the noise radius of the closest validated colony. In addition, to validate more of the potential colonies, a peak ratio of the peak pixel of the potential colony and the closest validated colony is computed and a radius ratio of the colony radius of the potential colony and the closest validated colony is computed. Then, the

5 potential colony is validated if the radius ratio exceeds a threshold radius ratio value, the peak ratio exceeds a threshold peak ratio value, the value of the peak pixel of the potential colony exceeds a threshold peak validation value, and the value of the colony radius of the potential colony exceeds a threshold radius validation value.

10 Each process of imaging the growth medium preferably includes determining a growth medium center where a typical growth medium is circular in shape. This growth medium center can be determined by performing edge detection in three regions of a colony image where the regions are located substantially between an edge and the center of the colony image. Subsequently, a first midpoint of a first

15 chord between detected edge points in a first region and a second region and a second midpoint of a second chord between detected edge points in said second region and a third region are computed. The growth medium center is determined as at the intersection of perpendicular bisectors of the first and second chords.

10 The identification of potential colonies from the difference image preferably includes locating the peak pixel within the difference image which has a local maximum pixel intensity and exceeds a threshold peak intensity value and determining gradients from the peak pixel in a predetermined number of directions. This locating of a peak pixel with a local maximum pixel intensity preferably occurs by scanning the difference image to locate seed pixels having an intensity value

25 greater than a threshold seed value, centering the top row of a box of predetermined box size over the seed pixel, identifying a centroid of several pixels as the maximum box pixel having the largest intensity value within the box, repositioning the box over the center of the maximum box pixel, continuing to scan for seed pixels and positioning a box over the maximum box pixel until the number of box moves

30 exceeds a predetermined maximum box move number or the maximum box pixel remains the same in two consecutive iterations, and then labeling the maximum box

pixel as the pixel peak. A peak pixel is then labeled as a potential colony if at least a minimum number of the gradients decrease over a minimum gradient distance. A colony radius is determined for the labeled potential colony. Subsequently, a mask, centered over the peak pixel, of a predetermined size is placed over the first colony 5 image. These potential colony identification steps are repeated for any pixels that are not already covered by masks centered over any of the previously identified potential colonies.

The determination of a colony radius for the peak pixel preferably includes scanning pixel values in a predetermined number of directions from the peak pixel. 10 Radius distances for each direction are computed until the radius distance equals a predetermined maximum radius distance, the pixel value is less than a threshold radius intensity value, or the pixel value exceeds the previously scanned pixel value by more than a predetermined noise value. Subsequently, a median value of the radius distances for the predetermined number of directions is computed and labeled 15 the colony radius.

The process of detecting and identifying microbial colonies may be further enhanced by centering a growth medium mask at the growth medium center. In addition, the process of determining a growth medium center may be repeated a plurality of times to obtain a plurality of growth medium centers and all of the 20 plurality of growth medium centers within a maximum center distance from each other are selected. Then, an averaged growth medium center is determined as a centroid of the selected growth medium centers. The growth medium mask is centered at the averaged growth medium center.

The process of detecting and identifying microbial colonies also may be 25 further enhanced by adding the number of validated colonies together to provide a total count of the microbial colonies in the growth medium. In addition, location data, size data, and colony growth rate data associated with each validated colony may be provided.

However, as will be appreciated by those skilled in the art other incubators 30 and imaging systems may be used in conjunction with the present invention without departing from the scope and spirit of the present invention.

FIG. 3 details a preferred embodiment user interface flow diagram that details the particular preferred sequence that the visual screen displays depicted in FIGS. 4, 5, 6, 7, 8 and 9 are shown on visual display 116.

Once computer 100 is powered up and the appropriate microorganism 5 culturing device monitoring software routines (hereinafter referred to as the "software") are initiated 200, a System Overview Screen 202 illustrated in Fig. 4 appears.

Before describing the details of this screen 202, it should be noted that common to all of the screens are the following:

- 10 • Menu - located at the top of every screen. It contains a list of commands used to operate the software. This feature eliminates the need for the user to memorize key sequences or commands to operate the system (i.e., everything is conveniently contained in these menus).
- 15 • Alarm Status - located near the bottom left corner of every screen is an area which shows the last active system alert. Clicking on this area with a mouse or other input device pops up a listing of all currently active alerts. As the user scrolls through this pop-up list, helpful information on what the alarm is and how to solve it will be presented to the user. This feature enables the operator to quickly identify problems and solve them.
- 20 • Date/Time - located near the bottom right corner of every screen is an area which shows the current date and time.
- 25 • Help Text - located near the bottom center of every screen is an area which shows context sensitive help information. As the cursor moves across the various objects on the screen, a line of text appears giving helpful tips on what the object is and/or how to use it. This feature allows even a novice user or one with very little training to quickly learn how to operate the software.
- 30 • Icons, Buttons, Lists, Fields, and other objects - every screen has a variety of objects used to present the user with information. Many of them also serve the dual purpose of accepting input from the user. For example, an Icon of the Printer Cable shows up as Red or Green, depending upon if

there is a problem with the printer communications or not. By clicking on it (via the mouse or other input device), the user is telling the computer 100 to go to the Printer Setup Screen. By using these pictures, icons, etc. to represent both data and commands, a more intuitive, easy to use interface is achieved. Indeed, many of the menu commands are not even needed, because the user simply points to the different screen elements (icons) and a command is executed and/or implemented.

10 The System Overview Screen 202 presents an overview of the status of the complete system. This allows the user to keep an eye on the status of the incubators, the computer, printer, database system, etc. Shown are:

15     • Computer Icon 220- this icon of a personal computer indicates the status of the computer running the software. It will be Green colored if all is OK, but turns Red colored if there is a problem. Clicking on this icon causes the software to show the Computer Setup Screen 210.

20     • Printer Cable Icon 222 - this double arrow shows the status of the connection to the printer hooked to the system. It will be Green colored if all is OK, but turns a Red color if there is a problem with the connection. Clicking on this icon causes the software to show the Printer Setup Screen (not shown).

25     • Printer Icon 224 - this icon of the printer shows the status of the printer itself. It will be Green colored if all is OK, but various parts turn a Red color if there is a problem (e.g., the paper part turns Red if the printer is out of paper).

   • Database Cable Icon 226 - this double arrow shows the status of the connection to an optional database computer hooked to the system. It will be Green colored if all is OK, but turns a Red color if there is a problem with the connection. Clicking on this icon causes the software to show the Database Communication Setup Screen 214.

- Database Icon 228 - this icon of the database computer shows the status of the database computer itself. It will be Green colored if all is OK, but turns a Red color if there is a problem (e.g., the database is inoperable).
- Incubator Icons 232 (1, 2, and 3) - these icons of the incubators show the status of the incubators and the culturing devices (i.e., preferably disposable thin film culturing devices) inside them. They are Gray colored if the incubator is not connected or otherwise not in use. If in use, it shows:
  - The type of specific culturing devices inside the Incubator (e.g., devices for coliform bacteria, yeasts and molds, etc.),
  - The number of Out-of-Spec culturing devices in a Red color,
  - The number of In-Spec culturing devices in a Green color,
  - The number of culturing devices still being monitored in a White color,
  - The total number of culturing devices in the incubator,
  - The total number of open slots available for adding new culturing devices, and
  - The temperature of the incubator.

By clicking anywhere on an Incubator Icon 232, the screen 204 (hereafter referred to as the "Incubator Screen") illustrated in Fig. 5 appears. This screen 204 presents a detailed look at the status of the selected incubator. Shown are:

- Computer 220, Printer Cable 222, Printer 224, Database Cable 226, and Database 228 icons as described above in reference to the System Overview screen 202.
- Return button 234 - clicking on this button returns the user back to the System Overview Screen 202.
- Culturing Device Icons 236- these icons show the current status of the culturing devices being monitored in the incubator. They may be, for example, arranged in a 10X10 matrix when one hundred devices are monitored. Each position on the screen corresponds to a position in the mechanical handling system inside the incubator. It will be appreciated by

those skilled in the art that the matrix on the screen can be reconfigured to correspond to any size or the handling system. This feature permits the user to - with just a glance - quickly scan the tests being conducted and easily determine which ones need attention. These icons have the following characteristics:

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- The number in the circle shows the current colony forming unit (CFU) count detected by the system for this culturing device.

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- The icon 236 is colored Red -including the inside circle - if the CFU count is greater than or equal to the HI Limit specified for this culturing device, and has not yet been acknowledged by the user.

- The icon 236 is colored Green if the CFU count is below the HI Limit and the incubation time has passed the Max. Time specified for this culturing device.

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- The icon 236 is colored Gray if the CFU count is below the HI Limit and the incubation time has not yet passed the Max. Time specified for this culturing device (i.e., it is still under observation).

- The icon 236 does not appear at all if there is no culturing device in the corresponding slot in the incubator's system.

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- The rectangle near the top of the icon 236 represents the elapsed incubation time for the culturing device. It has a time-bar fill in the rectangle as time goes by; the percentage filled shows the percentage of Max. Time which has elapsed.

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- Clicking on a Culturing Device Icon 236 via the mouse (or using some other input device such as a light pen) "selects" it. A colored rectangle surrounds the icon 236, and the CFU count number changes color. Selecting the icon 236 acknowledges an Out-of-Spec culturing device. Selecting an icon 236 also updates the "Culturing Device Details" panel 238 with the information on the associated culturing device.

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- Thermometer Icon 240 - this indicates the current temperature of the incubator. The "mercury" will be Green colored if the temperature is within the alarm tolerance of the set-point, and turns a Red color if outside this limit. The actual temperature is shown numerically on the side, and the set-point can be adjusted using the arrow controls at the bottom.
- Trash All Red button 242 - clicking on this button will eject all Out-of-Spec culturing devices from the incubator.
- Trash All Green button 244 - clicking on this button will eject all In-Spec culturing devices from the incubator.

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- The total number 246 of culturing devices in the incubator is also shown.
- The total number 248 of open slots available for adding new culturing devices is also shown.
- Culturing Device Details panel 238 - This area shows the following information of a selected culturing device:
  - Slot number (position inside the incubator).
  - Bar-code (if none was detected, "Unknown" is displayed).
  - Product, Type, Lot # - these are further descriptions to help identify the culturing device sample. Other labels/fields may be used depending upon how users identify samples.
  - HI Limit - specifies the count at which the culturing device is considered Out-of-Spec. This may be modified by the user.
  - Current # - shows the last CFU count detected by the system.

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- Max. Time - shows how long this culturing device should be monitored and ties in with the Out-of-Spec number for determining whether a culturing device is Out-of-Spec or In-Spec. This may be modified by the user.
- Entered on - shows the time at which the culturing device first entered the incubator.

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- Elapsed - shows how long the culturing device has been in the incubator.
- Picture - this shows a photo of the last image taken of the selected culturing device. Clicking on it causes the software to present the "Detailed View Screen" 206.
- Trash button - clicking on this button will eject the selected culturing device from the incubator.
- Binocular button - clicking on this button presents the "Detailed View Screen" 206.

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FIG. 6 illustrates screen 206 which presents a detailed look at a selected culturing device. Illustrated features are:

- Return button 250 - clicking on this button returns the user back to either the Incubator Screen 204 or the Table Screen 208 (depending on which screen invoked this Detailed View Screen 206).
- Culturing Device Details panel 238 - see the description above in the Incubator Screen 204 section.
- Graph 252 - shows the growth curve for the CFUs of the selected culturing device. CFUs are plotted along the Y-axis, time is plotted along the X-axis. It should be noted that additional "intelligence" may be added to work in conjunction with this graph. Such intelligence may perform "predictive" analysis based on historical information related to the sample groups to provide even earlier specification alerts to the user.
- Picture 254 - this shows an enlarged view of the photo of the last image taken of the selected culturing device. This permits the user to examine details in the sample without needing to open the incubator and handle the culturing device. This, in turn, aids in keeping the incubator at a more stable temperature (since the user won't be opening and closing the door as often). By clicking on this image, small circles are drawn at the coordinates of the click (the cursor turns to a cross-hair to assist in location identification). This feature allows the user to manually identify CFUs.

5                     •     **CFU Verification Counter 256** - as the user clicks on the culturing device picture, this area keeps track of the total number of circles. The count may be reset (and the associated circles erased) by clicking on the Reset button. This eliminates the user from having to remove the culturing device, place it under a Quebec counter, and manually count the various colonies using a hand-held counter.

By selecting "Table Screen" from the "View" menu, screen 208 is presented.

10                   FIG. 7 illustrates screen 208 which presents a tabular view of all of the culturing devices in the system. If more data exists than can be shown on one screen, scroll bars appear allowing the user to move through the table screen. At the top of the screen, controls are provided for:

15                   •     **Sorting 258** - three levels of sorting are selected by simply clicking on the list and choosing a desired sorting category. This feature permits the user to group the data based on a specific need. For example, the user can have it sorted such that all samples taken from "Production Line 1" are displayed together to facilitate an analysis on the cleanliness of that line.

20                   •     **Column Data selection 260** - optional categories (columns) can be shown/hidden in the table by clicking on the associated check box. This feature allows the user to view only the data needed.

                      •     **Row Data selection 262** - culturing device selection criteria (rows) can be chosen by clicking on the associated option button.

25                   The data in the table is a text-based representation of the information presented graphically in the Incubator Screen 204 described earlier. By double clicking on a particular row, the Detailed View Screen 206 is shown with the selected culturing devices information.

30                   Other support screens are provided by the software. One such screen is the Computer Setup Screen 210. FIG. 8 illustrates screen 210 which permits the user to specify date/time formats, set the date/time, select the language, establish auto-print options, buzzer preferences, and other computer related items. Another

screen 212, illustrated in FIG. 9, permits the user to specify which report layout to use for printing.

This present invention provides several advantages over existing systems, including but not limited to:

- 5         •         A system using culturing device technology which permits a visual readout as well as the software monitored count. Users can inspect the results by looking at an electronic image of the actual film.
- 10         •         A software interface structured such that all of the pertinent testing information is accessible via just one screen. And that one screen may be either in tabular or graphical form. There is no longer a need to remember convoluted key sequences to access the data and remember the information spread out across multiple screens. The interface has been designed such that minimal training will be required by the user. The present system's use of pictures, icons, buttons, etc. coupled with a built-in help system and minimal number of screens will have even a non-computer user up and running quickly.
- 15         •         An enlarged view of the culturing device in the Detailed View Screen eliminates the need for the user to remove the culturing device from an incubator and manually enumerate the various colonies. Providing this image also assists in stabilizing the incubator temperature, because all of the information about the culturing device is available to the user. As a result, the user does not need to continuously open and close the doors of the incubator, that results in temperature fluctuation, to view the culturing device.
- 20         •         A growth curve of CFUs facilitates predictive analysis once a history of such data has been collected.
- 25         •         A summary of the test results is presented in a manner as to allow the user to quickly ascertain which areas need attention. Any item "in alarm" is colored red, and the Alarm Summary area provides a consolidated look into the state of the system. By scanning for red, green as well as other colors the user is able to quickly determine the overall system status.

The present invention may be alternatively described in reference to the flowchart shown in FIGs. 10 and 11 that details the operation of the preferred embodiment user interface for displaying a microorganism colony in accordance with the present invention shown in FIG. 1. The preferred embodiment consists of

5 a computing device 100 coupled by a communication link to an incubator 102. Once a software control program is initiated 300, a disposable microorganism culturing device is moved 302 into position proximate an imaging device 106. A digitized image is electronically captured 304 from the disposable microorganism culturing device. The microorganism colonies in the digitized image are

10 enumerated 306 by a controller 114 into a colony count. It will be appreciated by those skilled in the art that the functions of controller 114 may alternatively be performed by a software routine programmed into computing device 100. This colony count along with a time of capturing the digitized image and an origin for the digitized image is stored 308 into a database. The use of a database in this

15 scheme provides tremendous flexibility and the ability to provide many desirable data processing features such as statistical analysis and reporting functions. As a part of this flexibility, the preferred embodiment includes the capability of exporting 310 information stored in the database to an external device so that the information may be used in other tasks such as quality control, plant logs, record keeping, and

20 the like.

The stored colony count is compared 312 to a predetermined value related to known parameters for the sample type being tested (e.g., a milk sample is compared to industry standards for colony counts in milk). The predetermined value may be unique for each individual disposable culturing device or common to

25 several devices in a rack that are from the same products, types, lots, samples, or based on other sample identifications which automatically link in testing specifications such as warning points, alarm levels, incubate times, or the like.

Subsequently, the digitized image, the colony count, and an associated status indicator are displayed 314 on a computer monitor 116 or similar device.

30 The particular status indicator which is displayed will depend on a result of the comparison to the predetermined value. For example, an alarm indicator may be

displayed, if the colony count is greater than the predetermined value. In addition, a warning indicator may be displayed when the colony count is less than the predetermined value, if the count is approaching the predetermined value or if the count has increased above a particular rate over a predetermined time (i.e., the colonies are growing rapidly). Finally, an okay indicator may be displayed, if the colony count is still less than the predetermined value and a predetermined time limit has lapsed (i.e., the incubation time is done).

5 This procedure for displaying a microorganism colony may be repeated 316 periodically for the same disposable microorganism culturing device such that 10 colony counts for several instances in time are obtained and stored in the database. Alternatively, this procedure for displaying a colony count may be repeated 318 for a plurality of disposable microorganism culturing devices such that several colony counts can be simultaneously displayed along with a summary section which details a status of each of the plurality of disposable microorganism culturing devices.

15 Another aspect of this displaying procedure is to provide a mechanism for manual verification 320, illustrated in FIG. 11, which is similar to the classic technique of counting colonies on a conventional pour plate. This electronic form of manual verification is provided by magnifying the displayed digitized image 322 and marking 324 a colony location with an input device (e.g., a light pen, mouse, 20 trackball, or touch screen,) on the displayed digitized image with a visual count being incremented automatically for each marked colony.

In addition, the preferred embodiment may be configured 326 to visually display additional information. Several types of additional information may be displayed 328 including: a graphical representation of the colony count versus time, 25 a digitized image identifier (e.g., a lot number or a bar code), a magnified version of the digitized image, a running total of manually marked colonies from a verification process in which each colony location is marked with an input device on the displayed digitized image, as well as a system status for various components such as a computer operational state, printer status, printer paper supply, data lines status, 30 database condition, and link to incubator status.

In yet another aspect of the present invention, a report production function 330 is provided. A report may be generated 332 including information stored in the database. These reports may be in tabular form which are sorted by various items available in the database. In addition, a query and/or report by type of sample may 5 be performed. This reporting function might archive all data for future trend analysis, exception reporting, or any other reporting needs (to state agencies or otherwise). Such archiving may also help reduce future occurrences of errors or waste. For example, if an archive was kept over the past year on when milk went sour and what were the circumstances including location in processing, which 10 supplier, time of day, and the like, then similar circumstances in the milk processing could readily be avoided and potential waste reduced.

Although the invention has been described and illustrated with a certain degree of particularity, it is understood that the present disclosure of embodiments has been made by way of example only and that numerous changes in the 15 arrangement and combination of parts as well as steps may be resorted to by those skilled in the art without departing from the spirit and scope of the invention as claimed.

## Claims

1. A method of displaying a microorganism culturing device, comprising
  - (a) electronically capturing a digitized image from a microorganism culturing device;
  - (b) enumerating microorganism colonies in the digitized image into a colony count;
  - (c) storing the colony count along with a time of capturing the digitized image and an origin for the digitized image which is associated with the colony count into a database; and
  - (d) displaying the digitized image and colony count.
2. The method of claim 1 wherein steps (a) to (d) are repeated periodically for the microorganism culturing device such that colony counts for sequential instances in time are obtained and stored in the database.
3. The method of claim 1 wherein steps (a) to (d) are repeated for a plurality of disposable microorganism culturing devices.
- 20 4. The method of claim 1 wherein the displaying step comprises simultaneously displaying a plurality of colony counts and a summary status of each of the plurality of microorganism culturing devices.
5. The method of claim 1 wherein the step of displaying comprises an additional visual display selected from the group consisting of:
  - (a) a graphical representation of the colony count versus time;
  - (b) a digitized image identifier;
  - (c) a magnified version of the digitized image;
  - (d) a running total of manually marked colonies from a verification process in which each colony location is marked with an input device on the displayed digitized image; and

(e) a system status for components selected from the group consisting of a computer operational state, printer status, printer paper supply, data lines status, database condition, and link to incubator status.

5 6. The method of claim 1 wherein the displaying step further comprises:

(a) displaying an alarm indicator based on a result of the comparing step, if the colony count is greater than a predetermined value;

10 (b) displaying a warning indicator based on a result of the comparison step, if the colony count is less than the predetermined value, but proximate the predetermined value;

(c) displaying a warning indicator based on a result of the comparison step, if the colony count is less than the predetermined value, but the colony count has increased above a particular rate over a predetermined time; and

15 (d) displaying an okay indicator based on a result of the comparison step, if the colony count is less than the predetermined value and a predetermined time limit has lapsed.

7. A method of displaying a microorganism culturing device, comprising

20 (a) electronically capturing a digitized image from the microorganism culturing device;

(b) enumerating microorganism colonies in the digitized image into a colony count;

(c) storing the colony count along with a time of capturing the digitized image and an origin for the digitized image into a database;

25 (d) comparing the stored colony count to a predetermined value; and

(e) displaying the digitized image, colony count, and an associated status indicator based on a result of the comparing step, the particular status indicator being selected from a group consisting of:

30 (i) an alarm indicator, if the colony count is greater than the predetermined value;

(ii) a warning indicator, if the colony count is less than the predetermined value, but proximate the predetermined value;

5 (iii) a warning indicator, if the colony count is less than the predetermined value, but the colony count has increased above a particular rate over a predetermined time; and

(iv) an okay indicator, if the colony count is less than the predetermined value and a predetermined time limit has lapsed.

8. The method of claim 7 wherein the step of displaying comprises an  
10 additional visual display selected from the group consisting of:

(a) a graphical representation of the colony count versus time;

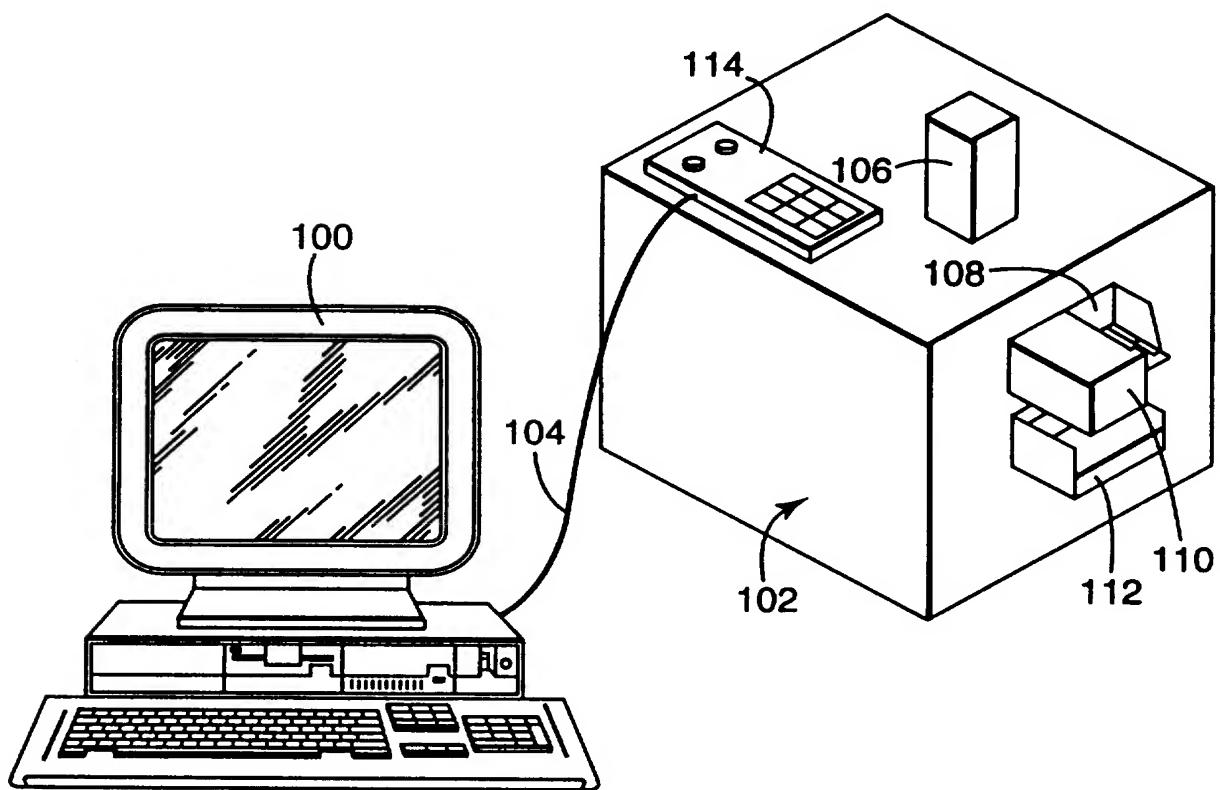
(b) a digitized image identifier;

(c) a magnified version of the digitized image;

15 (d) a running total of manually marked colonies from a verification process in which each colony location is marked with input device on the displayed digitized image; and

(e) a system status for components selected from the group consisting of a computer operational state, printer status, printer paper supply, data lines status, database condition, and link to incubator status.

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**Fig. 1**

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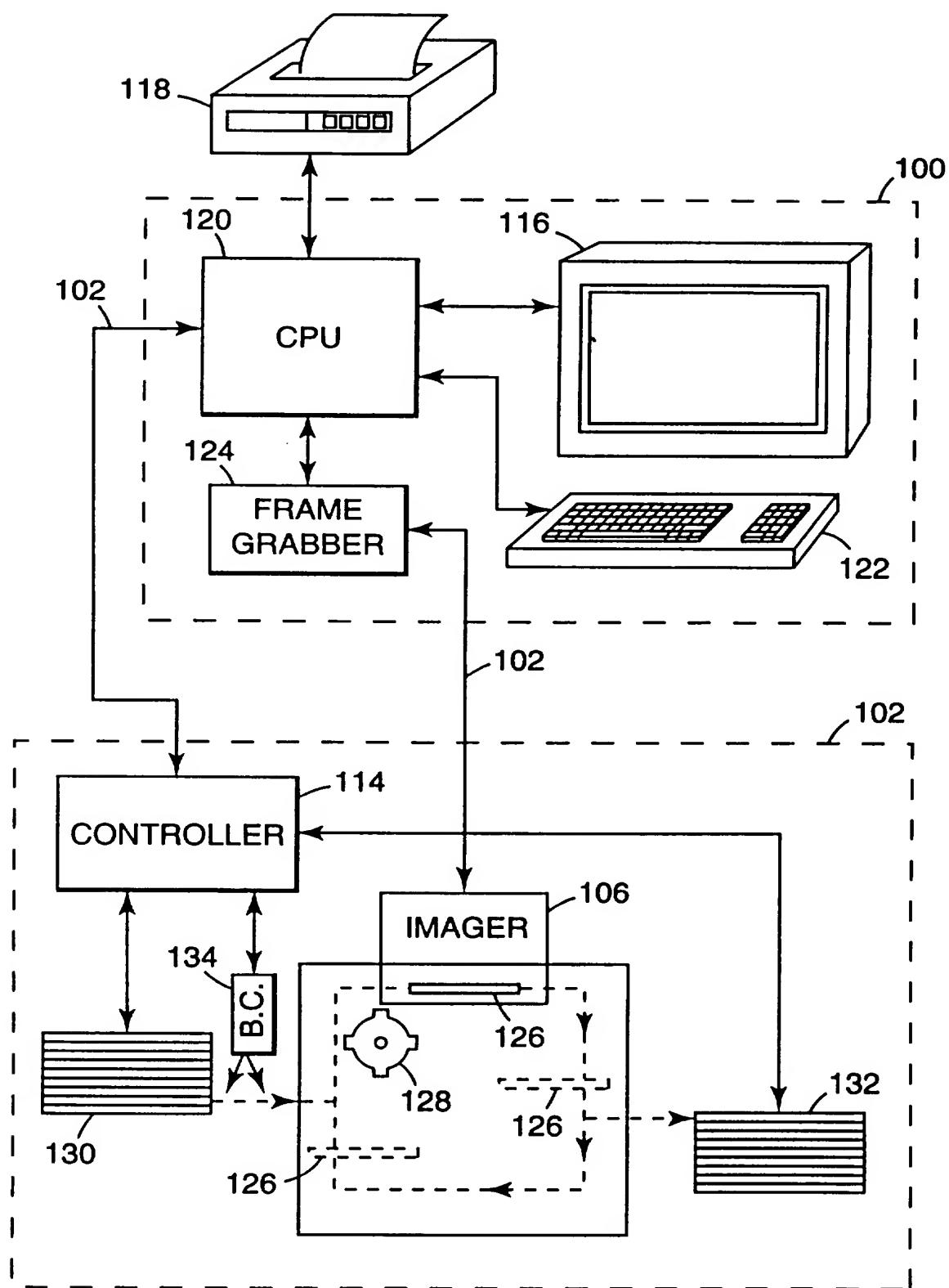


FIG. 2

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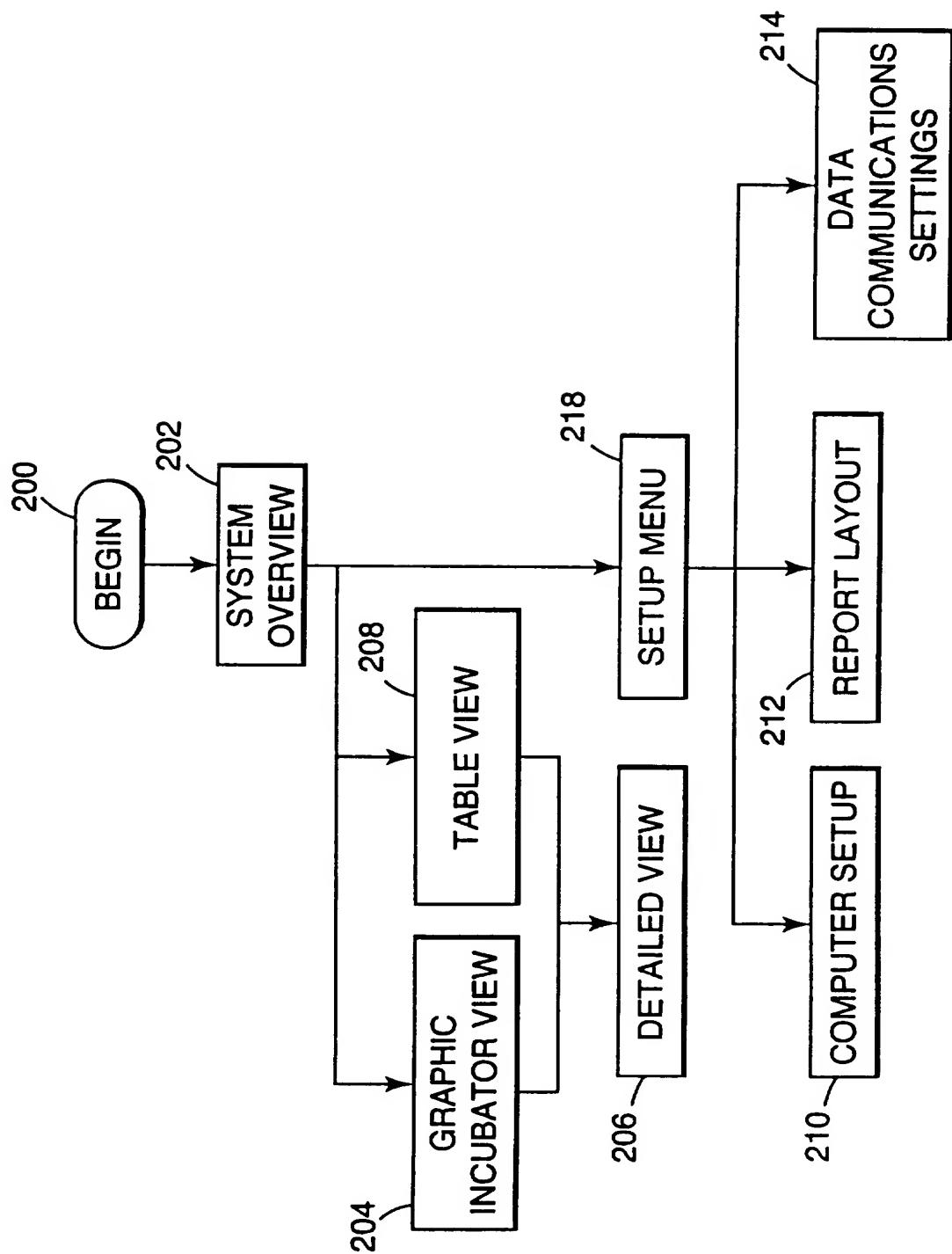


FIG. 3

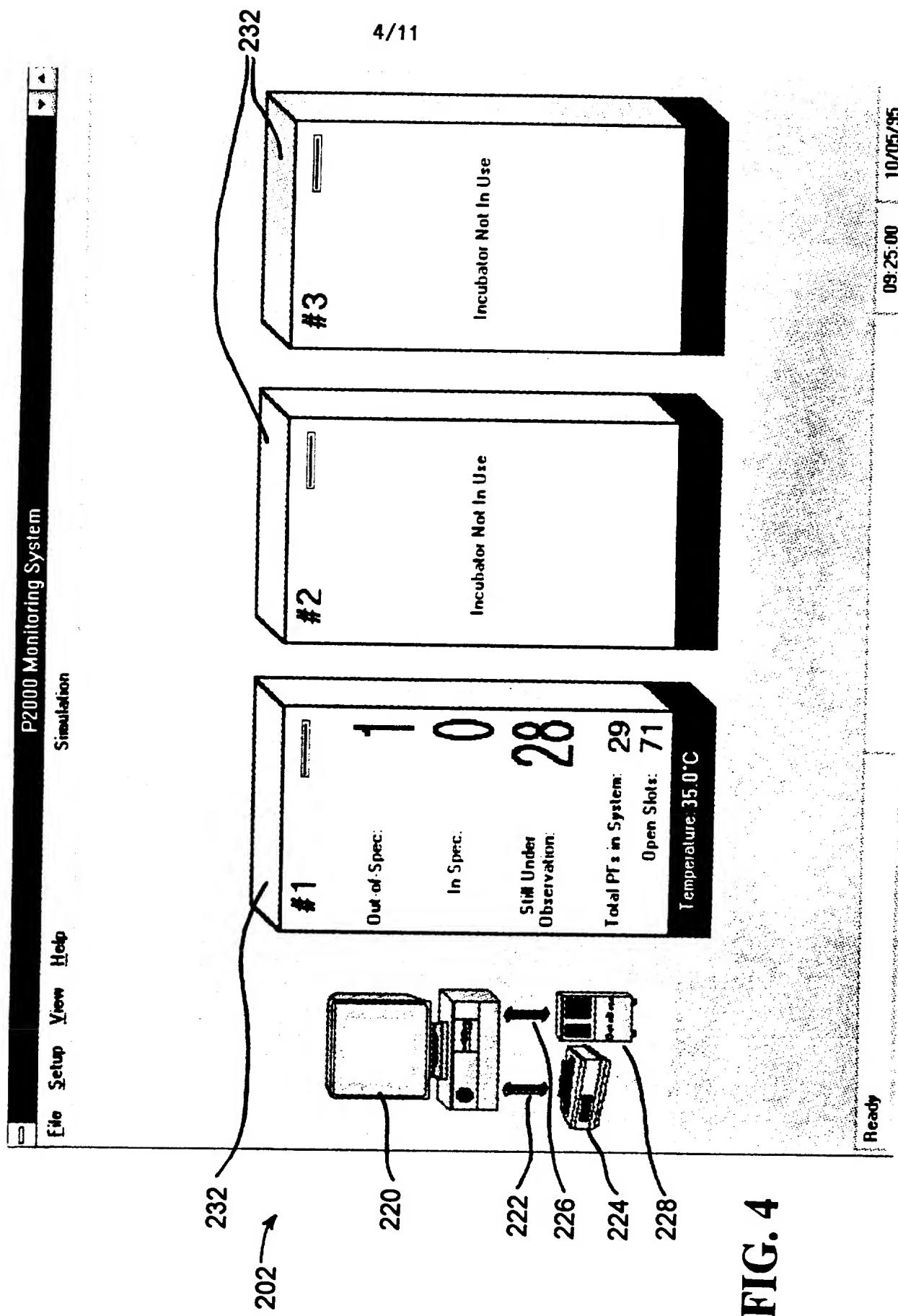


FIG. 4

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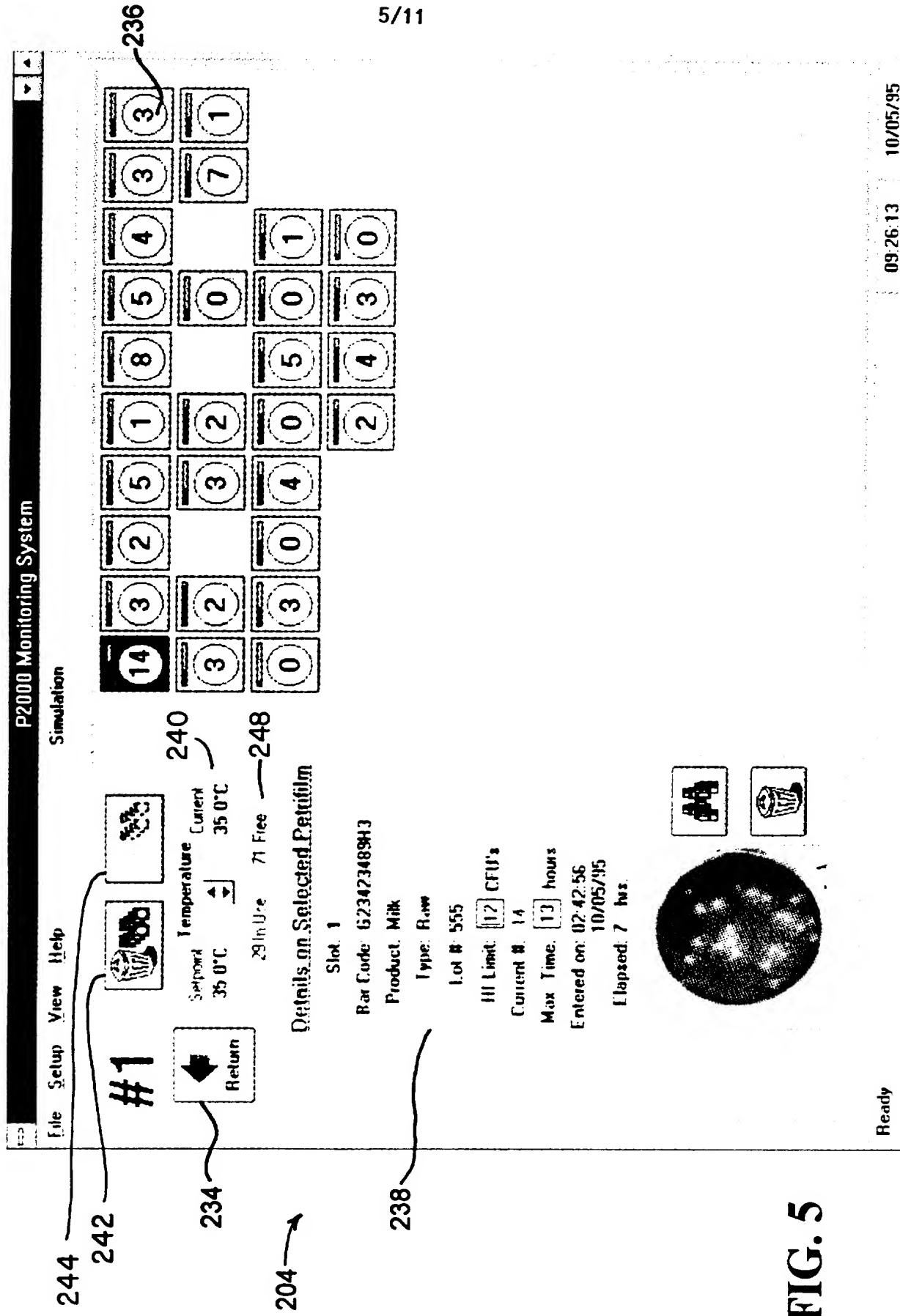


FIG. 5

254

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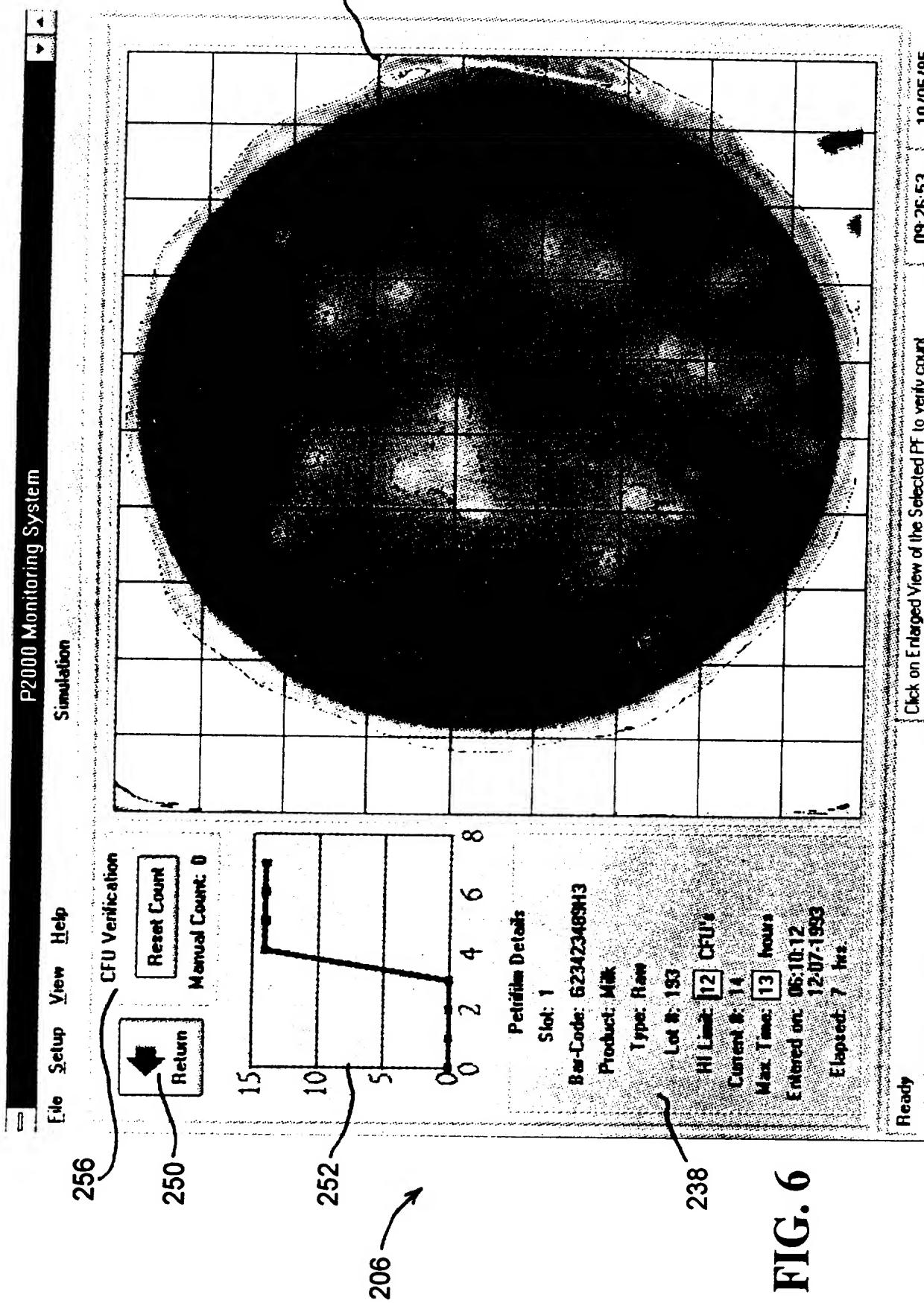


FIG. 6

258 → 208 → 260 → 262 → 7/11

Sort By: 1. Product 2. Type 3. CFUs

File Setup View Help

Simulation

Data to Show (Columns):  Lot  Bar-code  Product  InTime  Limit Delta  Entered  All Slots  Filled Slots  Expired  Out-of-Spec  In-Spec  InSpec+OutSpec  Observing

Permissions to Show (Rows):  All Rows  CFUs Limit  Delta InTime Elapsed  Entered

Slot Lot BarCode Product Type CFUs Limit Delta InTime Elapsed Entered

Slot	Lot	BarCode	Product	Type	CFUs	Limit	Delta	InTime	Elapsed	Entered
25	4312	Unknown	Cheese	Cheese	0	10	0	10	12	8
26	329	Unknown	Cheese	Cheese	5	10	-5	12	8	3/2/94
20	123	Unknown	Cheese	Baby Swiss	1	10	9	20	8	3/2/94
22	123	Unknown	Cheese	Baby Swiss	3	10	10	20	8	3/2/94
8	654	6923429J3	Cheese	Baby Swiss	4	10	9	20	6	3/2/94
19	2423	Unknown	Cheese	Baby Swiss	7	10	7	14	8	3/2/94
12	234	333	Cheese	Swiss	2	7	-22	24	22	3/2/94
6	5654	623342343	Cheese	Swiss	8	10	6	18	10	3/2/94
27	906	Unknown	Milk	Milk	0	5	5	12	7	3/2/94
24	321	Unknown	Milk	Milk	4	10	6	12	8	3/2/94
21	444	Unknown	Milk	Dry	0	4	7	24	2	3/2/94
5	123	623342347	Milk	Dry	1	4	-1	17	10	3/2/94
4	123	623342347	Milk	Dry	5	6	-3	16	10	3/2/94
14	345	321	Milk	Processed	3	10	6	26	9	3/2/94
3	322	623423489H3	Milk	Raw	2	5	3	15	9	3/2/94
9	??	Unknown	Milk	Raw	3	6	2	21	7	3/2/94
2	432	623423489H3	Milk	Raw	3	12	0	14	7	3/2/94
1	555	623423489H3	Milk	Raw	14	12	0	13	7	3/2/94
15	345	Unknown	Yogurt	Yogurt	2	10	8	11	9	3/2/94
37	511	B23489J38	Yogurt	Banana	3	10	9	15	11	3/2/94
36	511	B23489J38	Yogurt	Banana	4	10	9	14	11	3/2/94
10	546	Y213429H3	Yogurt	Blueberry	3	6	2	22	8	3/2/94
11	345	Unknown	Yogurt	Blueberry	3	6	3	23	8	3/2/94
7	21	Y213429H3	Yogurt	Blueberry	5	10	6	19	10	3/2/94

Select which columns to show in the table.

Ready

09-29-02

10/05/95

FIG. 7

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**P2000 Monitoring System**

**Computer Setup Screen**

**File** **Setup** **View** **Help**

**Return**

**Date Format**

dd/mm/yy    dd/mm/yy/mm    dd/mm/yy/yy

dd/mm/yy/yy    MMM. dd. yy    yy/mm/dd

MMM. dd. yy/yy    dd-MMM-yy    dd-MMM-yy/yy

Example: 10/05/95

**Time Format**

12 Hour    24 Hour

Show Seconds

Example: 09:30:34

**Set Time**

**Print Options**

Auto Print    Out Of Spec

**Language**

Dutch    German    Spanish

English    Italian    Swedish

French    Pig Latin

**Buzzer Preferences**

Enable Buzzer

210

Ready

210

**FIG. 8**

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212→

**Report Layout Screen**

File   Setup   View   Help   Simulation  

**Pre-Defined Templates**

Daily Detail Summary    Current Detail Summary  
 Daily Line Summary    Current Line Summary  
 Single PF Details    Custom

**Automatic Data Items**

Current Date    Current Time  
 \* Out of Spec    Details on Out of Spec  
 \* In Spec    Details on In Spec  
 \* TBD    Details on TBD  
 Page #    System ID

**Manual Entry Items:**

Notes    Report Title  
 Comments    Operator Name

Page 1

Customize your report

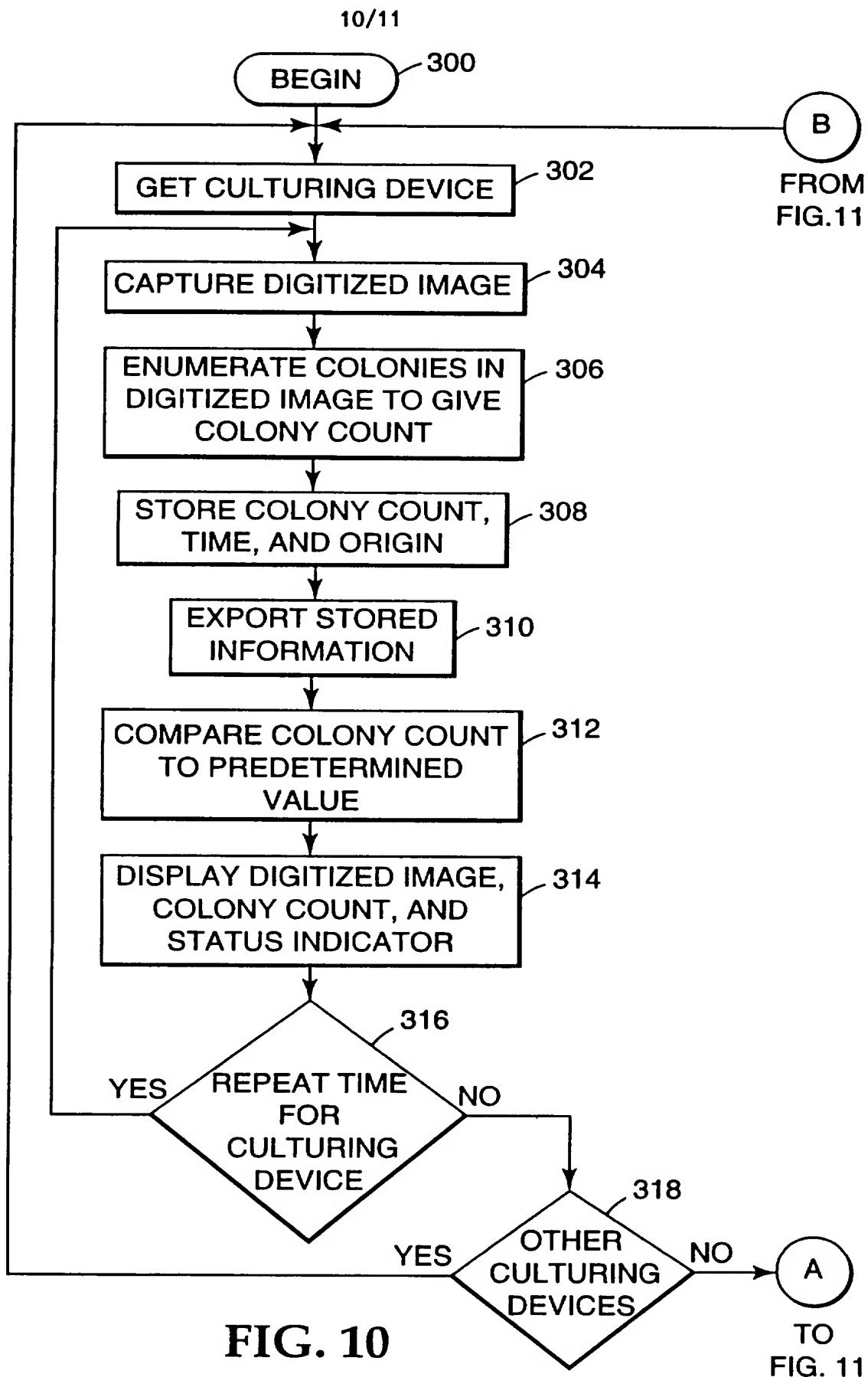
Ready

09:31:37   10/05/95

**Example Report**

**Please Enter Your Title Here NOW**

**FIG. 9**



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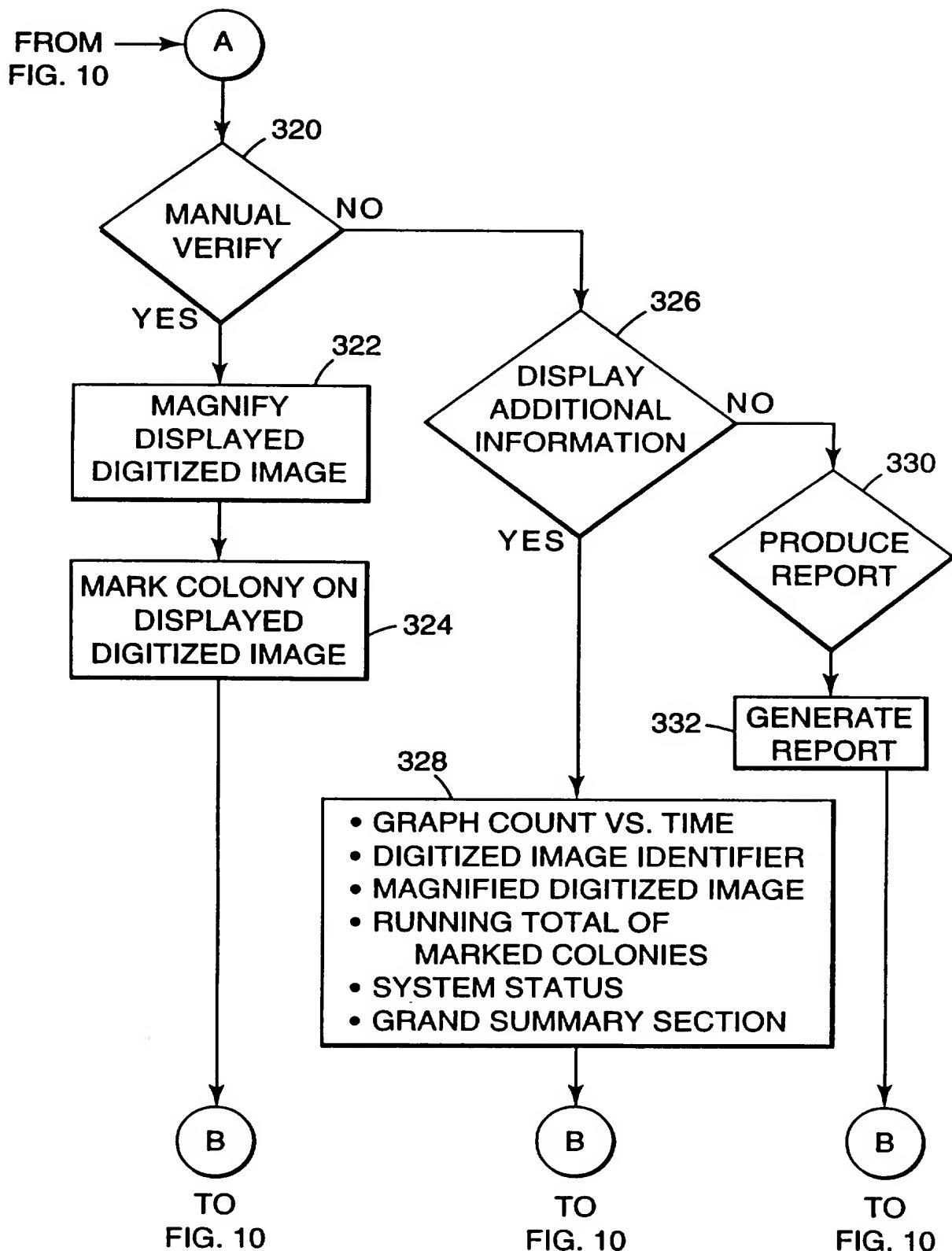


FIG. 11

**INTERNATIONAL SEARCH REPORT**

International Application No

PC1/US 95/16335

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 C12M1/34

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 C12M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 290 701 (J. R. WILKINS) 1 March 1994 cited in the application see column 5, line 50 - column 6, line 25; claims 1,10 see column 7, line 2 - line 18 see column 7, line 66 - line 68 ---	1-5,7,8
Y	US,A,3 811 036 (RUSSELL C. PERRY) 14 May 1974 see claims; figures ---	1,6-8
Y	US,A,5 270 173 (FUMIHIKO YONEMORI ET AL.) 14 December 1993 see claims; example 1 -----	1,6-8
Y	US,A,5 270 173 (FUMIHIKO YONEMORI ET AL.) 14 December 1993 see claims; example 1 -----	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- 'A' document defining the general state of the art which is not considered to be of particular relevance
- 'E' earlier document but published on or after the international filing date
- 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- 'O' document referring to an oral disclosure, use, exhibition or other means
- 'P' document published prior to the international filing date but later than the priority date claimed

- 'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- 'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- 'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- '&' document member of the same patent family

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Date of the actual completion of the international search  
25 April 1996

Date of mailing of the international search report

02.05.96

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Authorized officer

Coucke, A

**INTERNATIONAL SEARCH REPORT**International Application No  
PCT/US 95/16335

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5290701	01-03-94	NONE		
US-A-3811036	14-05-74	JP-C-	1092762	16-04-82
		JP-A-	49070669	09-07-74
		JP-B-	56020591	14-05-81
US-A-5270173	14-12-93	CA-A-	1325475	21-12-93
		WO-A-	8903431	20-04-89